

K960054

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510(k) SUMMARY

510(k) Submission K960054

IRIS 900UDx™ Urine Pathology System

General Information:

Date of Submission: December 30, 1995

Trade Name of Device: 900UDx Urine Pathology System

Common Name of Device: Automated urinalysis system

Classification Name: Automated urinalysis system,
21 CFR 862.2900, Class I
Microscope, 21 CFR 862.3600, Class I

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Intended Use: The 900UDx Urine Pathology System performs routine urinalysis, including urine chemistry, specific gravity, and sediment microscopic examination.

Substantial Equivalence to Predicate Device: The 900UDx Urine Pathology System is substantially equivalent under Section 510(k) of the Food, Drug, and Cosmetic Act to The Yellow IRIS® Urinalysis Workstation with CHEMSTRIP® Reader, and the IRIS Flow Microscope.

Summary of Technological Characteristics: The 900UDx Urine Pathology System provides automatic sample handling for automated intelligent microscopy and improved data presentation and management. Specimens are

aspirated by an autosampler rather than poured manually. Microscopic examination results are displayed on an independent ViewStation computer with higher image resolution, and operators can confirm and release reports off-line for enhanced convenience. Chemistry results from the external Boehringer Mannheim Hitachi CHEMSTRIP® Super UA Urine Analyzer™ are automatically consolidated by the ViewStation for display and reporting.

Performance Studies:

Microscopic analysis performance of the 900UDx Urine Pathology System was compared with that of The Yellow IRIS Urinalysis Workstation.

**Conclusions Drawn
From Clinical Tests:**

Detection of RBC, WBC, squamous epithelial cells, pathologic casts, and yeast was found to be equivalent to that of the predicate device. The 900UDx Urine Pathology System had greater sensitivity for detection of renal epithelial cells and crystals as well as for overall detection of abnormal urines. Reproducibility was equivalent to that of the predicate device. The 900UDx Urine Pathology System has been shown to be suitable for its intended use.